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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/590,884	06/09/2000	Erika Hawkins	341.014US1	1643

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EXAMINER
CHAUDHRY, MAHREEN F

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 11/23/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/590,884	Applicant(s) HAWKINS ET AL.	
	Examiner Mahreen Chaudhry	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-75* is/are pending in the application.

4a) Of the above claim(s) *58-75* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *58-75* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the claims

1. Acknowledgement is made of the amendment filed August 29, 2001. Claims 1, 3 and 15 have been amended. Claims 35-75 have been added.

Election/Restrictions

2. Newly submitted claims 58-75 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 1-57 and claims 58-75 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because multiple classes of organic compounds may be utilized to practice the instant method. For example, claims 61 and 64 each recite chemically distinct compounds which may be utilized to practice the instant invention. The subcombination has separate utility in other combinations.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Claims 1-57 would be classified in class 435, subclass 8. Claims 58-75 would be classifed in multiple classes and subclasses including at least class 534, subclass 12 and class 568, subclass 18. In addition, claims 58-75 are directed to multiple

patentably distinct species and would require election of a single disclosed species for purposes of examination.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 58-75 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-34 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-~~57~~ 34 are indefinite with regard to the term "an organic compound" since it is unclear what specific organic compounds are to be utilized in the recited methods and kits. The term "organic compound" is broad and encompasses more than the specification could possible support.

Applicant argues that since the term "organic compound" is known to indicate compounds "comprising one or more carbon atoms," the term is not indefinite. Applicant additionally contends that since the specification provides examples of suitable organic compounds, the term "organic compound" is not indefinite.

not asking for a def of organic compounds

It is the examiner's position that the term "organic compound" is indefinite since it is does not adequately define a specific chemical compound or specific class of chemical compounds appropriate for utilization in the recited methods and kits. The claims define such chemical compounds functionally without any recitation of a specific chemical structure beyond the fact that such compounds are organic. The term "organic compounds" is unduly broad especially in view of the examples of suitable organic compounds provided in the specification. It would be impossible for one having ordinary skill in to determine the metes and bounds of the chemical compounds to which the instant claims are directed with a mere recitation of the functional attributes of the chemical compounds in the absence of their chemical structures.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-3, 8-12, 16-21, 35-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 07067696A published by Mitoma et al. Mitoma et al. disclose a method of reducing background luminescence by treatment of haem and peroxidase with luminol and hydrogen peroxide in the presence of organic compounds such as citric acid which reduce background luminescence and increase sensitivity of measurement (abstract). Mitoma et al. do not expressly disclose the source of background luminescence or an amount by which such luminescence is reduced. Mitoma et al. teach a method of decreasing background luminescence in

chemiluminescent reaction and do not specifically disclose a method for decreasing background in a bioluminescent reaction. However, it would have been obvious to one having ordinary skill in the art to have reduced background luminescence from any source using an organic compound as taught by Mitoma et al. since Mitoma et al. teach a general method of reducing background luminescence with specific organic compounds. It would additionally have been obvious to one having ordinary skill in the art to have reduced background luminescence by a desired amount by utilizing an appropriate quantity of such specific organic compound.

Applicant contends that the instant invention is distinguished from that of Mitoma et al. in that Mitoma et al. does not teach increasing the sensitivity of a luminescent assay wherein luminescence occurs the action of an enzyme on a substrate. Applicant alleges that Mitoma et al. would not have provided one having ordinary skill with a reasonable expectation of success that the disclosed compounds could increase the sensitivity of luminescent reaction in which luminescence was generated by the action of an enzyme on a substrate.

It is the examiner's position that Mitoma et al. is directed to an assay in which luminescence occurs by the action of an enzyme on a substrate. Mitoma et al. discloses that background luminescence is reduced by including compounds with specific functional groups in an assay in which a luminous reaction is measured in a peroxidase based reaction with a dihydrophthalazinedione derivative as a substrate. Since Mitoma et al. does teach an assay in which luminescence is generated by the action of an enzyme, peroxidase, on a substrate, the dihydrophthalazinedione derivative, and Mitoma et al. discloses specific chemical compounds that may be utilized to decrease background luminescence in such reactions, one having ordinary

skill in the art would certainly have had a reasonable expectation of success that background luminesence could be reduced using the compounds specifically disclosed by Mitoma et al.

5. Claims 1-3, 8-31, 34-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,629,168 issued to Kricka. Kricka discloses that the presence of specific organoboron compounds enhance chemiluminescence in the reaction involving luminol, hydrogen peroxide and peroxidase. Kricka discloses that the presence of the organoboron compounds increases the signal:background ratio in chemiluminescent reactions and that improving the signal:background ratio is important in improving the sensitivity of the assay (Column 3, Lines 50-65). Kricka additionally discloses that the concentration of the enhancer as between 0.01 uM and 4 M (Column 6, Lines 25-31). Kricka teaches a kit including luminol, peroxidase and an organoboron enhancer (Column 4, Lines 58-60; Column 14, Lines 19-33). Kricka further discloses that the signal:background ratio increased with increasing concentration of specific organoboron compounds (Column 7, Table 1). Kricka teaches that the improvement in signal:background ratio was attributable to the reduction in background light emission by specific organoboron compounds (Column 8, Lines 18-24). Kricka does not expressly teach the reduction of background light emission from any specific source. Additionally, Kricka teaches a method for decreasing background luminescence in chemiluminescent reaction and does not specifically teach such a method in bioluminescent reactions. However, it would have been obvious to one having ordinary skill in the art to have utilized the method taught by Kricka for reducing background luminescence from any source and thus increase luminescent assay

sensitivity since Kricka teaches a general process for increasing the signal:background ratio and decreasing background.

Applicant contends that the instant invention is distinguished from that of Kricka et al. in that Kricka et al. does not teach increasing the sensitivity of a luminescent assay wherein luminescence occurs because of the action of an enzyme on a substrate. Applicant alleges that Kricka et al. would not have provided one having ordinary skill with a reasonable expectation of success that the disclosed organoboron compounds could increase the sensitivity of luminescent reaction in which luminescence was generated by the action of an enzyme on a substrate.

It is the examiner's position that Kricka et al. is directed to an assay in which luminescence occurs by the action of an enzyme on a substrate. Kricka et al. discloses that background luminescence is reduced by including organoboron in an assay in which luminous reaction is measured in a peroxidase based reaction with luminol as a substrate. Since Kricka et al. does teach an assay in which luminescence is generated by the action of an enzyme, peroxidase, on a substrate, luminol, and Kricka et al. discloses organoboron compounds that may be utilized to decrease background luminescence in such reactions, one having ordinary skill in the art would certainly have had a reasonable expectation of success that background luminesence could be reduced using the compounds specifically disclosed by Kricka et al.

6. Claims 1-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,814,471 issued to Wood. Wood discloses a method for improving the kinetics of light production from luciferase activity. Wood discloses that the presence of thiol reagents including dithiothreitol results in a decrease in peak intensity and an increase in the total light emitted

during a luciferase reaction (Column 5, Lines 52+; Column 8, Lines 51-63). Wood discloses test kits including a luciferase-luciferin composition, ATP, a thiol reagent and a buffer solution which may be combined in a single container or in several containers (Column 10, Lines 39-67). Wood further discloses that a luciferase composition with improved kinetics of light production includes an aqueous solution comprises beetle luciferase, CoA, a thiol reagent at a concentration between 10 and 100 mM and peak-intensity reducing compounds (Column 5, Lines 37-45; Column 13, Lines 24-35). Wood teaches that the luciferase assay may be conducted using cells (Column 9, Lines 32-48). Wood does not expressly disclose that the sensitivity of the assay is increased by reducing luminescence due to autoluminescence, luminogenic molecules and independent of the presence of analyte. However, Wood does disclose that the presence of thiol reagents results in a decrease in the peak intensity of light. It would therefore have been obvious to one having ordinary skill in the art to have utilized thiol reagents such as those taught by Wood to increase assay sensitivity since Wood teaches that thiol reagents decrease peak intensity and improve the kinetics of light production. Wood does not specifically disclose assays include Renilla luciferase or Cypridina luciferase, however, Wood does teach the use of beetle (firefly) luciferase and since both Renilla luciferase and Cypridina luciferase are well-known in the art, it would have been obvious to one having ordinary skill in the art to have utilized either Renilla luciferase or Cypridina luciferase in the method taught by Wood.

Applicant argues that Wood et al. does not disclose a method of decreasing unwanted luminescence and therefore does not obviate the instant invention. However, it is the examiner's position that Wood et al. does obviate the instant invention since Wood et al. is directed to the inclusion of organic compounds in a bioluminescent reaction for the purpose of improving the

kinetic of luminescence produced by a luciferase reaction. The claims recite "a method for increasing the sensitivity of a bioluminescent assay comprising carrying out the assay in the presence of an organic compound..." The method disclosed by Wood et al. would be encompassed by such a method. Since applicant does not provide any structural characteristics of the recited organic compound and merely discloses its functional characteristics, the method taught by Wood et al. of including a thiol containing compound in a luciferase reaction in order to improve luminescence characteristics would obviate the method as claimed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mahreen Chaudhry whose telephone number is (703) 605-1200. The examiner can normally be reached on Monday – Friday (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached on (703) 308-1701 . The official fax phone number for the organization where this application is proceeding or assigned is (703) 308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

mc
November 7, 2001

RALPH GITOMER
PRIMARY EXAMINER
GROUP 1200